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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,411	11/16/1999	Nathalie B. Scholler	730033.409	4284

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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/04/2002 22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/441,411	SCHOLLER ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2002 and 18 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The amendment filed September 18, 2002 (Paper No. 20) has been entered. The amendment filed August 21, 2002 (Paper No. 19) has been entered. Claims 1-8 have been amended. Claims 9-11 have been newly added. The amendment filed September 18, 2002 (Paper No. 20) has been entered. Claims 10 and 11 have been amended.

Accordingly, Claims 1-11 are pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 21, 2002 (Paper No. 19) has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 3-8 of the Office Action of Paper No. 5 (mailed 4/12/00) and on pages 2-6 of the Office Action of

Paper No. 10 (mailed 1/4/01), because the specification, while being enabling for a composition for eliciting or enhancing the titer of antibodies for Her2/neu protein, wherein the composition comprises individual expression constructs which each recombinantly express Her2/neu, murine B7.2 or murine 4-1Bb ligand, does not reasonably provide enablement for other compositions for eliciting or enhancing the titer of antibodies for any cell surface receptor antigen, wherein the composition comprises one or more recombinant expression constructs which express (either as individual expression vectors, a single expression vector, or a combination thereof), any cell surface receptor antigen plus two immune response altering molecules, consisting of any accessory cell agent and any T cell agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

At page 5 of the response, Applicants assert that the present application satisfies the requirements of 35 U.S.C. 112, first paragraph. Applicants argue that the state of the art, the relative skill of those in the art, and the guidance presented in the specification enable the claimed compositions. Applicants further argue, pointing to Donnelly et al., that at the time of filing of the instant application, DNA constructs were successfully used to elicit protective antibody and cell-mediated immune responses. However, the instantly claimed invention is directed to expression constructs that encode three different agents, each of which must be delivered to the appropriate site and expressed at a level appropriate to elicit the desired effect, *i.e.* eliciting antibodies specific for the cell surface receptor antigen encoded by the expression construct. The claimed composition is comprised of one or more expression constructs. Thus, gene delivery with subsequent gene expression at a level and location appropriate to elicit the desired response is a critical aspect of the invention. Furthermore, as the design and development of this type of composition is inherently unpredictable, one skilled in the art would not be able to produce similar compositions for other SRAs, using other immune response altering molecules (IRAMs), without undue experimentation. While the specification presents a vast array of IRAMs that may be used in the present

invention, the specification only provides a starting point (*i.e.*, the scope of enablement indicated above) for identifying other embodiments of the claimed invention that will elicit the claimed response, but the specification does not provide guidance on the direction in which experimentation should proceed. Absent specific guidance for identifying other compositions that produce the claimed response, the skilled artisan would have been required to engage in trial and error experimentation. Such experimentation clearly would rise to the standard of undue experimentation.

At page 6 of the response, Applicants assert that a lack of understanding of parameters such as the level and location of gene expression, the fate of the DNA vector, and trafficking of the DNA does not render Applicants' invention unpredictable because such parameters are not essential to the subject matter of the invention. No support is offered for this assertion. However, absent specific guidance regarding which combinations of IRAMs, whether T cell agent or accessory cell agent, to use with a particular cell surface receptor antigen, to which one hopes to provoke a humoral response, the skilled artisan would have been left to experiment by trial and error, with no clear guidelines on the direction in which experimentation should proceed. The courts have stated that "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). However, in the instant case, there is no teaching of the direction in which experimentation should proceed and trial and error experimentation does not constitute routine experimentation.

It is not to be left up to the skilled artisan to figure out how to make the necessary starting materials and then to figure out how to use them to produce the biological effects as recited in the claims. The courts held that the disclosure of an application shall inform those skilled in the art how to use applicant's claimed invention, not how to **find out** how to use it for themselves. *In re Gardner et al.* 166

USPQ 138 (CCPA 1970). This specification only teaches what is intended to be done and how it is intended to work, but does not actually teach how to do that which is intended.

At page 6 of the response, Applicants admit that the result of eliciting an antibody response using compositions as claimed, was an unexpected result. In view of the fact that the result was unexpected, one of skill in the art would not know how to go about identifying other embodiments that would produce this same unexpected result, over the broad range of combinations of antigens and IRAMs covered by the claims.

The court has recognized that physiological activity is unpredictable. *In re Fisher*, 166 USPQ 18 (CCPA 1970). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved. *In re Fisher*, 166 USPQ 18 (CCPA 1970).

At page 7 of the response, Applicants argue that since Freund's adjuvant can be used with multiple antigens, by analogy, one skilled in the art would expect that the claimed composition comprising a nucleic acid sequence encoding an SRA other than the one exemplified in the working example would elicit an antibody response. Applicants go on to state that one skilled in the art could readily realize the effect of interchanging an SRA according to the instant claims. However, the **claimed** invention is directed to constructs encoding an SRA plus a first and second IRAM. Thus, testing other combinations would require much more than "interchanging an SRA" as Applicants contend here. Rather, the skilled artisan would end up testing a vast array of combinations of antigen with any 2 IRAMs. Otherwise, the skilled artisan would be limited to using the combination of agents exemplified in the specification and testing other antigens to determine if the same effect can be achieved for constructs encoding other cell surface receptor antigens. However, the claims are very broad in scope covering any combination of the three components. Applicants arguments are not commensurate in scope with the claimed invention.

Given the limited working examples directed to a single combination of antigen plus a first and second IRAM, the limited guidance in the specification with regard to identifying other combinations that would produce the claimed effect, the broad scope of the claims, and the unpredictability of using the claimed methods to achieve the claimed effect, undue experimentation would have been required for one skilled in the art to use the claimed compositions over the full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 11 are indefinite in their recitation of the SEQ ID Nos. placed in parentheses because it is unclear if the SEQ ID Nos. are actual claim limitations or just exemplary matter.

Allowable Subject Matter

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. See MPEP § 706.07(a).

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE BAKER
PATENT EXAMINER